K032514

JAN 27 2004

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
SYNERON MEDICAL Ltd. AC applicator

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

Submitter: Syneron Medical Ltd., Sultam Industrial park, P.O.B. 550, Yokneam Elite 20692, Israel.

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Name of the Device: AC applicator

Predicate Devices: AC applicator is substantially equivalent to a combination of the following devices: Aurora SR, manufactured by Syneron Medical Ltd. and subject of K031993. ClearLight phototherapy device, manufactured by CureLight and subject of K013623. Omnilux Blue, manufactured by Photo Therapeutics limited and subject of K030883. Smoothbeam laser system, manufactured by Candela Corp. and subject of K014128.

Device Description: The AC applicator is a device that is used for the treatment of moderate inflammatory acne vulgaries. The AC applicator treatment is based on the principle of *selective (electromagnetic) thermolysis combined with photochemical reaction of the acne bacteria.* According to this principle, parameters of optical and RF energy (spectrum, exposure duration and energy density) are chosen and optimized to selectively damage acne bacteria and the sebaceous glands without damaging the surrounding tissues.

The AC applicator is intended for the treatment of moderate inflammatory acne vulgaries.

Based upon an analysis of the overall performance characteristic for the device, Syneron Medical Ltd. believes that no significant differences exit. Therefore the AC applicator should raise no new issues of safety or effectiveness.

August 12, 2003

Date

Amir Waldman

Dr. Amir Waldman,
Director regulatory affairs
Syneron medical Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 27 2004

Dr. Amir Waldman
Director Regulatory Affairs
Syneron Medical Ltd.
Sultan Industrial Park
P.O.B. 550 Yokneam Elite
20692, Israel

Re: K032514
Trade/Device Name: AC Applicator, Aurora AC
Regulation Number: 21 CFR 878.4810, 21 CFR 878.4400
Regulation Name: Laser Surgical Instrument for Use in General and Plastic Surgery and in Dermatology, Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: II
Product Codes: GEX, GEI
Dated: November 13, 2003
Received: November 17, 2003

Dear: Dr. Waldman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known) K 032514

Device Name AC applicator.

Indications For Use:

The AC applicator indicated for the treatment of moderate inflammatory acne vulgaries.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over The Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Miriam C. Provost

Restorative
Devices

K032514